

Excerpts from 180 NAC 17 for Veterinary Facilities

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APRIL 12, 2003 REGULATION AND LICENSURE 180 NAC 17

TITLE 180 CONTROL OF RADIATION

CHAPTER 17 ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING
PROCEDURES FOR LICENCEES AND REGISTRANTS; PENALTIES

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TITLE 180 CONTROL OF RADIATION

CHAPTER 17 ENFORCEMENT OF RADIATION CONTROL ACT AND RIGHTS TO HEARING
PROCEDURES FOR LICENSEES AND REGISTRANTS; PENALTIES.

17-001 SCOPE AND AUTHORITY: 180 NAC 17 governs the conduct of proceeding under the Radiation Control Act, the administrative procedures of the Agency and the Formal Hearing Procedures of the Department of Health and Human Services Regulation and Licensure, for the issuing, denying, renewing, transferring, amending, suspending, revoking of any license, registration or certification of persons to use radiation sources and for determining compliance with or granting of exemptions from Agency rule, order, or condition of license or certification of persons; for assessing administrative penalties; and for determining content of other agency orders. Proceedings held under the Radiation Control Act will be governed by the Rules of Practice and Procedure of the Department of Health and Human Services Regulation and Licensure, 184 NAC 1, except as provided below. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3519.

17-002 DEFINITIONS: Terms used in 180 NAC 17 have the following definitions:

Act means the Radiation Control Act as defined in the Nebraska Revised Statutes.

Applicant means a person seeking a license or certificate of registration or a person's certification to use radiation sources issued under the provisions of the Act and these rules.

Deliberate misconduct means an intentional act or omission by a person that (a) would intentionally cause a licensee, registrant, or applicant for a license or registration to be in violation of any rule, regulation, or order of or any term, condition or limitation of any license or registration issued by the department under the Radiation Control Act or (b) constitutes an intentional violation of a requirement, procedure, instruction, contract, purchase order, or policy under the Radiation Control Act of a licensee, a registrant, an applicant for a license or registration, or contractor or subcontractor of a licensee, registrant or applicant for a license or registration.

Certificate of Registration means a document issued pursuant to the Act and rules promulgated thereunder.

Civil Penalty means a monetary penalty assessed by the Agency under 71-3517 of the Act.

Contested Case means a proceeding in which the Agency determines the legal rights, duties, or privileges of a party after an opportunity for adjudicative hearing.

Discipline means the imposition by the Agency of a sanction, including revocation, suspension, limitation, condition, or civil penalty.

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Enforcement Conference is a meeting held by the Agency with licensee/registrant management to discuss safety, safeguards, or environmental problems; the licensee's/registrant's compliance with regulatory, license condition, or registration condition requirements; a licensee's/registrant's proposed corrective measures (including, but not limited to, schedules for implementation); and enforcement options available to the Agency.

Hearing is a proceeding to examine an application or other matter before the Agency in order to receive information or to adjudicate rights, duties, or privileges.

Hearing Examiner means a person selected by the Director of Regulation and Licensure to conduct hearings.

Interested person is a person who participates in a hearing concerning a contested case but who is not admitted as a party by the Hearing Examiner.

Notice of Violation is a written statement of one or more infringements of a legally binding requirement. The notice normally requires the licensee/registrant to provide a written statement describing:

Corrective steps taken by the licensee/registrant, and the results achieved;

Corrective steps to be taken to prevent recurrence; and

The projected date for achieving full compliance.

Order means a specific directive contained in a legal document issued by the Agency.

Party is a person designated as such by the Hearing Examiner. A party may consist of the following:

The Agency;

An applicant/licensee/registrant; and

Any person affected.

Person affected means a person:

Who is a resident of a county, or a county adjacent to the county, in which radioactive materials subject to the Act are or will be located, including any person who is doing business or who has a legal interest in land in the county or adjacent county, and any local government in the county; and

Who shall demonstrate that he/she has suffered or will suffer actual injury or economic damage.

Preliminary Report is a document prepared by the Agency containing:

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A statement of facts on which the Agency bases the conclusion that a violation has occurred;

Recommendations that an administrative penalty be imposed on the person charged; and

Recommendations for the amount of that proposed penalty.

Public Hearing means a proceeding which shall be open to the public, for the purpose of hearing testimony or receiving written statements from any person who chooses to offer information on the subject matter set for hearing, conducted after notice to the public of the time, date, and place of the hearing.

Requestor is the designation of a person claiming party status as a person affected.

Severity level means a classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety or the environment.

Violation is an infringement of any rule, license or registration condition, order of the Agency, or any provision of the Act.

17-003 PUBLIC HEARINGS

17-003.0 The Agency will hold public hearings

In any proceeding for the issuance or modification of rules or regulations relating to control of sources of radiation, the agency will provide an opportunity for public participation through written comments and a public hearing.

17-003.02 Public Hearing on Applications

1. Procedure

- a. The Agency will provide a public hearing for an application for a license for licensing ores processed for their source material content and management of byproduct material and source material mill tailings, or for licensing management of low-level radioactive waste.
- b. The Agency will issue public notice of the public hearing and provide opportunity for written comments. A transcript of the hearing and a written determination will be available of the action to be taken based on the findings of the evidence presented during the public hearing and public comment period. Agency staff, the hearing officer and applicant may ask questions of any witness testifying at the public hearing.

2. Environmental Impact Analysis

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- a. When the Agency determines that the issuance, amendment or renewal of a license to manage, process or dispose of low-level radioactive waste as defined in Neb. Rev. Stat. § 71-3503(23) of the Act or process materials resulting in byproduct material as defined in Neb. Rev. Stat. § 71-3503(13)(b) of the Act will have a significant impact on the public health and safety and environment, the Agency will secure a written analysis of the impact from the applicant or licensee, and the Agency will prepare a written statement on the analysis and make them available to the public for written comment at least thirty (30) days before holding the public hearing on the issuance, amendment or renewal of a license.
 - b. The analysis will assess the radiological and nonradiological impact on the public health and the impact on the total environment. It will consider the alternatives to the issuance, amendment or renewal of the license, including long term impacts of the licensing action may have on radioactive materials remaining at the site after decommissioning and reclamation.
 - c. Any major construction is prohibited by the applicant for a license before the environmental impact analysis has been completed and a report filed and a license issued.
3. Prior to termination of a license issued after public hearing in compliance with 180 NAC 17-003.02, item 1 the Agency shall assure that the licensee has :
 - a. Complied with the decontamination, decommissioning and reclamation standards established by the Agency, as set out in 180 NAC 12.
 - b. Transferred ownership of the site to the State of Nebraska or the United States Government; and
 - c. Made adequate funding arrangements to provide for long term surveillance and care of the site.

17-004 RESERVED

17-005 DISCIPLINE

17-005.01 Any person who violates any provision of the Radiation Control Act, or any rule, regulation, or order issued pursuant to such Act, or any term, condition, or limitation of any license, registration, or certificate issued pursuant to such Act or has engaged in deliberate misconduct shall be subject to:

Revocation, is denial, suspension, modification, condition or limitation;

The imposition of a civil penalty; or

The terms of an appropriate order issued by the Agency.

17-005.02 Compliance

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1. In all instances other than the issuance of emergency sanctions pursuant to 180 NAC 17-008, the Agency may afford the licensee, registrant or certificate holder the opportunity to:
 - a. Correct violations and show compliance with applicable provisions of the Act, or the rules and regulations, license or registration requirements, and any orders of the Agency issued thereunder, or
 - b. Attend an enforcement conference to discuss with the Agency methods and schedules for correcting the violation(s) or to show compliance with the Act, rules and regulations and license conditions. Notice of any enforcement conference will be sent by personal service or certified mail, return receipt requested. An enforcement conference is not a prerequisite for any action.
2. The Agency may permit the licensee or registrant, or certified individual to respond in writing to the alleged violation of the Act, rule, regulation, order, or any term, conditions of limitation of license or registration.
3. Failure of a licensee or registrant to respond is cause for the Agency to proceed with disciplinary action.

17-006 HEARINGS : Whenever the Agency proposes to subject a licensee or registrant to the provisions of 180 NAC 17-005.01, the Agency will notify the person in writing, (a) setting forth the date, facts, and nature of each act or omission with which the person is charged, (b) specifically identifying the chapter, rule, regulation, order, license or registration certificate involved in the violation and (c) of the sanction or order to be imposed. If a civil penalty is imposed, the notice shall include a statement that it can be collected by civil action. The notice shall be delivered to each alleged violator by personal service, by certified or registered mail to his or her last known address, or by publication. Notice by publication shall only be made if personal service or service by mail cannot be effectuated. The sanction or order in the notice shall become final thirty days after the mailing of the notice unless the applicant, registrant, or licensee, within the thirty-day period, requests, in writing, a hearing before the department. If the notice is served by personal service or publication, the sanction order shall become final thirty days after completion of such service unless the applicant, registrant, or licensee, within the thirty-day period, requests, in writing, a hearing before the department.

17-007 SANCTIONS

17-007.01 The Department may consider the following:

1. **Criteria in determining what sanctions are appropriate:**
 - a. Previous history of noncompliance;
 - b. Action necessary to deter future violations;
 - c. Lack of reasonable efforts to correct the violation(s);
 - d. Willfulness; and
 - e. Any other aggravating factors.

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2. The severity levels: The seriousness of violations will be categorized by one of the following severity levels:
 - a. Severity Level I - Violations that are most significant and have a direct negative impact on occupational and/or public health and safety or on the environment.
 - b. Severity Level II - Violations that are very significant and have an impact on occupational and/or public health and safety or on the environment.
 - c. Severity Level III - Violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.
 - d. Severity Level IV - Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances affecting public health and safety.
 - e. Severity Level V - Violations that are of minor public health and safety or environmental significance.
3. Examples of violations in each severity level(s) are set out in Appendix 17-A of 180 NAC 17.

17-007.02 Civil Penalties: May impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000) for each violation a day. If any violation is a continuing one, each day a violation continues may be considered a separate violation for purposes of penalty assessment. Table 1 provides examples for civil penalties.

TABLE I
Examples of
Civil Penalty Base

Amounts Based on Severity Level of Violations

Severity Level	Amount
I	\$5,000
II	\$3,000
III	\$1,500
IV	\$ 500
V	\$ 100

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Adjustments to the amounts in Table I may be made for the presence of the criteria set out in 180 NAC 17-007.01, item 1.

17-007.03 Suspension and Revocation of a License or Registration: In addition to the other factors set out in 180 NAC 17-007, used by the Agency to determine appropriateness of license revocation or suspension, the Agency may act to suspend or revoke a license or a registration if a person:

1. Knowingly causes a material misstatement or misrepresentation to be made in the application for license or registration if such misstatement would impair the Agency's ability to evaluate the applicant's qualifications, or
2. Willfully aids another person in violating the Act or these regulations.

17-008 EMERGENCY SANCTIONS: In the event of an emergency requiring immediate action to protect the occupational or public health and safety, or the environment, the Agency may immediately, without prior notice or hearing:

1. Issue a regulation or order citing the existence of such emergency and require that certain actions be taken to meet the emergency:
 - a. An emergency regulation or order takes effect immediately upon service on the person to whom the order is directed.
 - b. Any person receiving such emergency regulation or order must comply immediately.
2. If the Agency determines that a person possessing sources of radiation is not equipped to observe or fails to observe the provisions of the Act or these rules and regulations, then the Agency may impound or order the impounding of the sources of radiation:
 - a. An order of impoundment takes effect immediately upon service on the person to whom the order is directed. An impoundment takes effect immediately, and service on the affected person of notice of impoundment or of an order of impoundment will be made as soon as is practical under the circumstances.
 - b. Any person receiving an order of impoundment will comply immediately.
3. Service of any regulation order, or other notice or pleading under 180 NAC 17 will be made by personal service or by certified mail, return receipt requested. Affidavit of service, proof of mailing to the proper address, or the return receipt is evidence of service.
4. Hearings on Emergency Sanctions
 - a. A hearing will be held on an emergency regulation or order pursuant to 180 NAC 17-008 item 1 or upon an impoundment or order of impoundment pursuant to 180 NAC 17-008 item 2 if the person to whom the regulation or order or impoundment is directed makes a written application to the Agency for a hearing; said

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- application must be filed within fifteen (15) days of receipt of the emergency regulation or order of impoundment or notice of impoundment.
- b. The hearing must be held not less than fifteen (15) days nor more than thirty (30) days after filing the written application for hearing.
 - c. Whenever a person has requested a hearing pursuant to 180 NAC 17-008 item 4 the Agency will notify the person in writing, setting forth the time, date and place at which a hearing will be held. The notice must be served in accordance with 180 NAC 17-008 item 3 on the applicant not less than ten (10) days before the time set for the hearing.
 - d. On the basis of the evidence presented at the hearing, the Director or his/her designee shall, within thirty (30) days after such hearing, continue, modify or revoke the emergency regulation or order of impoundment or order of impoundment that was the subject of the hearing, and the Department shall send the applicant a copy of its findings of fact and determination.
5. Any final department action on emergency regulations or orders or impoundment of sources of radiation is be subject to judicial review pursuant to the Administrative Procedure Act.

17-009 DELIBERATE MISCONDUCT:

17-009.01 Any licensee, registrant, applicant for a license or registration, employee of a licensee or registrant, contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, or employee of any contractor or subcontractor to a licensee, registrant, or applicant for a license or registration, who knowingly provides to any licensee, registrant, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities covered by the Radiation Control Act, shall not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the Agency; or
2. Intentionally submit to the Agency, a licensee, a registrant, an applicant, or a licensee's, registrant's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

17-009.02 Any person who violates 180 NAC 17-009, is subject to the provisions of 180 NAC 17-005.

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EXAMPLES OF SEVERITY LEVELS

The following examples of severity levels apply to licensees or registrants and are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

A. Severity I - Most Significant Violations.

1. Exposure of a worker in excess of 250 mSv (25 rems) of radiation to the whole body, or 1.50 Sv (150 rems) to the skin of the whole body, or 3.75 Sv (375 rems) to the feet, ankles, hands, or forearms;
2. Annual whole body exposure in excess of 25 mSv (2.5 rems) of radiation to a non-radiation worker or a radiation worker who is a minor;
3. Release of radioactive material to an unrestricted area(s) in excess of ten times the limits specified in the rules;
4. Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the rules;
5. Disposal of licensed material into a sanitary sewage system in quantities or concentrations which exceed ten times the limits of 180 NAC 4-041;
6. Exposure of a worker in a restricted area(s) to ten times the limits of 180 NAC 4-005;
7. A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or not operable due to a deliberate act by the licensee or registrant (e.g., bypassing an interlock);
8. A material false statement. This is a written or sworn statement that is false and is relevant to the regulatory process;
9. Action by management to discriminate against an employee for attempting to communicate or for actually communicating with the Agency pursuant to 180 NAC 10-007.03;
10. Deliberate exposure of an individual except by or under the supervision of an individual licensed to engage in the healing arts;
11. Refusing authorized Agency personnel access to facilities and/or equipment to conduct inspections or investigations; or
12. Possession of licensable quantities of radioactive material without a license.

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B. Severity II - Very Significant Violations.

1. Single exposure of a worker in excess of 50 mSv (5 rems) of radiation to the whole body, 300 mSv (30 rems) to the skin of the whole body, or 750 mSv (75 rems) to the feet, ankles, hands or forearms;
2. Annual whole body exposure in excess of 5 mSv (0.5 rem) of radiation to a non-radiation worker or radiation worker who is a minor;
3. Release of radioactive material to an unrestricted area in excess of five times the limits of 180 NAC 4-014;
4. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the rules;
5. Failure to immediately notify the Agency as required by 180 NAC 4-057, item 1 and 3, 4-056.01 item 1 and 2;
6. Unauthorized disposal of licensed material in quantities or concentrations in excess of five times the limits of 180 NAC 4-041;
7. Exposure of a worker in a restricted area in excess of five times the limits 180 NAC 4-005;
8. A required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable;
9. Failure to obtain appropriate Agency approval before moving to a new use and/or storage location;
10. A material false statement. This is a statement that is false by omission and is relevant to the regulatory process;
11. Radiation output on fluoroscopic devices which exceed the limits in 180 NAC 6-005.03, item 1.
12. Absence of patient exposure reduction equipment required by Title 180.
13. Refusing authorized Agency personnel access to records during an inspection or investigation upon reasonable notice;
14. Loss of control of a source of radiation; or
15. Failure to register sources of radiation or services as required by these rules.

C. Severity III - Significant Violations.

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1. Single exposure of a worker in excess of 30 mSv (3 rems) of radiation to the whole body, or 75 mSv (7.5 rems) to the skin of the whole body, or 187.5 mSv (18.75 rems) to the feet, ankles, hands or forearms;
2. A radiation level in an unrestricted area such that an individual could receive greater than 1.0 mSv (100 millirems) in a one-hour period or 5.0 mSv (500 millirems) in any seven consecutive days;
3. Failure to notify the Agency within 24 hours as required by 180 NAC 4-058.02 or failure to notify the Agency within 30 days as required by 180 NAC 4-057.01, item 2 or 4-59;
4. Substantial potential for an exposure or release in excess of the limits of 180 NAC 4 (e.g., entry into high radiation areas without performing an adequate survey; operation of a radiation facility with a nonfunctioning interlock system);
5. Release of radioactive material to an unrestricted area in excess of the limits of 180 NAC 4-014;
6. Unauthorized disposal of licensed material not covered in Severity Levels I or II;
7. Exposure of a worker in restricted areas in excess of the limits of 180 NAC 4-005;
8. Release for unrestricted use of radioactive material or contaminated equipment which poses a potential for significant exposure to members of the public, or which reflects a programmatic rather than isolated weakness in the radiation safety program;
9. Cumulative worker exposure above Title 180 limits when such exposure reflects a programmatic rather than an isolated weakness in the radiation safety program;
10. Conduct of licensee or registrant activities by an unauthorized or an unqualified person;
11. Any noncompliance with posting, labeling, placarding, shipping papers, packaging loading, or other transporting requirements that could result in the following:
 - a. Improper identification of the type, quantity, or form of material,
 - b. Failure of the carrier or recipient to exercise adequate controls, or
 - c. Substantial potential for personnel exposure or contamination, or improper transfer of material;
12. Failure to control access to licensed materials as specified by Agency rules;
13. Possession or use by licensee or registrant of unauthorized radiation machine or radioactive material in conducting registrant or licensee activities;

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14. Radiation levels, contamination levels, or releases that exceed the limits specified in the license;
 15. Failure to use exposure reduction devices properly (e.g., collimators, filtration); or
 16. Failure to hospitalize patients who have sealed source implants or therapeutic quantities of radioactive material in accordance with the license or license conditions;
- D. Severity IV - Violations.
1. Exposure in excess of the limits of 180 NAC 4-005 not constituting Severity I, II, or III violations;
 2. A radiation level in an unrestricted area such that an individual could receive greater than 0.02 mSv (2 millirems) in any one-hour period or 1.0 mSv (100 millirems) in any year;
 3. Failure to notify the Agency within 30 days as required by 180 NAC 4-059.
 4. Failure to make a follow-up written report to the Agency as required by 180 NAC 4-057.02, 4-063 or 10-004.
 5. Failure to conduct required leakage or contamination tests or to use properly calibrated equipment.
 6. Unless specified in a more severe category, changes in procedures or other conditions of a license or certificate of registration of which the Agency was not informed (e.g., change of address, expiration of certificate of registration); or
 7. Failure to maintain complete records and/or forms required by Nebraska's Regulations for Control of Radiation - Ionizing.
- E. Severity V - Minor Violations.
1. Failure to maintain a current copy of Title 180 and current copies of active licenses and/or certificates of registration;
 2. Failure to post Title 180 notices required by 180 NAC 10-002; or
- Other violations that have minor safety or environmental significance.